

Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

March 4, 2015

ZONARE Medical Systems, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street, NW BUFFALO MN 55313

Re: K150249

Trade/Device Name: ZS3 and z.one_{pro} Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX Dated: February 2, 2015 Received: February 3, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<u>http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</u> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

| (k) Number (If known) | |
|---|---|
| K150249 | |
| Device Name | |
| ZS3and z.one _{pro} Ultrasound Systems | |
| | |
| Indications for Use (Describe) | |
| The ZS3 and z.one PRO Ultrasound Systems are intended for use by Fetal/obstetric, gynecological; Abdominal (renal, GYN/Pelvic; Intra neurological; Pediatric: small organ (thyroid, breast, testes, etc), Adr Trans-esophageal (non-cardiac and cardiac); Musculosketal (conven Echo, Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and | -operative (abdominal, moracic, and vascular), intra-operative ult & Neonatal Cephalic; Trans-rectal, Trans-vaginal, Trans-cranial tional & superficial); 3D/4D; Cardiac - Adult/ Pediatric/ Fetal; |
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| | |
| Type of Use (Select one or both, as applicable) | |
| Prescription Use (Part 21 CFR 801 Subpart D) | Over-The-Counter Use (21 CFR 801 Subpart C) |
| CONTINUE ON A SEPAR | ATE PAGE IF NEEDED. |
| This section applies only to requirements | of the Paperwork Reduction Act of 1995. |
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Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

510(k) Number (if known)

Device Name

System: ZS3 and $z.one_{pxo}Ultrasound$ Systems Transducer: System union of all transducer types

Indications for Use (Describe)

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| office (Paynol(e illoid | CONTRACTOR OF THE PROPERTY OF | 14.1 | | Ou - | | Color | Combined | Other ^{5, 8} |
|---|---|--------------|--------------|------------------|--------------------------------------|----------------------|--|--|
| Jeneral Track 1 Only) | Specific (Tracks 1 & 3) | В | · M | PWD ² | CMD | Doppler ³ | Modes ⁴ | Onto |
| Ophthalmio | Ophthalmic | P | | P | | P | | P ⁵ |
| уримими | Fetal | P | P | P | P | P | | P ⁵ |
| | Abdominal | P | P | P | P | P | Modes ⁴ P P P P P P P P P P P P P P P P P P | <u> </u> |
| | Intra-operative | P | P | P | | P | | P ⁵ |
| | (Specify) ⁶ Intra-operative (Neuro) | P | | P | | P | P | P ⁵ |
| | Laparoscopic | | | | | | | |
| | Pediatric Pediatric | P | P | P | P | P | P | P ⁵ |
| | Pediatric Aux | | - | | P | | | |
| | Small Organ (Thyroid, | P | P | P | | P | P | P ⁵ |
| | Breast, Testes, etc.) | | | | D | P | р | P ³ |
| | Neonatal Cephalic | P | P | P | P | P | | P ⁵ |
| etal Imaging & | Adult Cephalic | P | P | P | P | P | 1.7 | P ⁵ |
|)ther | Trans-rectal | P | P | P | | P | | P ⁵ |
| | Trans-vaginal | P | P | P | ļ . —— | F | 1 | |
| | Trans-urethral | | · | | | - | | P5 |
| | Trans-esoph. (non- Card.) | ·P. | P | Р | .P | P . | P | ļ - |
| | Musculo-skel. (Conventional) | .P | P | P | .51 | P | P | P 5, 8 |
| | Musculo-skel. | P | p | P | | P | . P | P 5, 8 |
| | (Superficial) | | | 1 | | 1 1 | | |
| , | Intravascular | | | 1 1 1 1 | | P | р | |
| | Other (Specify) (3D/4D and Contrast) | P | P | P | | P | 1 | P ⁵ |
| | Cardiac Adult | P 1 | P | Р | P | P | F | + |
| | Cardiac Adult Aux | | | | P | 1 | - D | P ⁵ |
| | Cardiac Pediatric | P | P | P | P | P | F | |
| | Cardiac Pediatric Aux | | <u> </u> | | P | - | l D | P ⁵ |
| Cardiac | Trans-esoph: (Cardiac) | P | P | P | P | P | 1 | * |
| | Other (Speoify) | P | P | P | Ρ. | . P | P | |
| | (3D/4D) Other (Intra-Cardiac)* | P | P | P | | P | | P3: |
| | Peripheral Vessel | P | . p | P | P | P | P | P ⁸ |
| Destudent Mangal | Peripheral Vessel Aux | ┤── | | | Р | | - 01 c 200 | |
| Peripheral Vessel | Other (Specify) | р | - | 7 | | P | P 4 | |
| • • | (3D/4D) | 1.7 | P | P . | | <u> </u> | F 75 | |
| ¹ Includes B-Mode ² Includes PWD-M | dication; P = previously clear and Harmonic (contrast) im ode imaging and High Pulse oppler (CD), Directional Po B+PW, B+CD+PW, B+M, N | Repetitio | n Rate P | WD-Mode (| HPRF) Doppler (Pl storgrapgh a | D) nd +ECG trace | , Andrews | |

⁵ Color M-Mode (CM) ⁶ Abdominal includes renal, GYN/Pelvic

Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

8 Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

510(k) Number (if known)

Device Name

System: ZS3and z.one_{pro}Ultrasound Systems Transducer: Curvilinear Transducer C4-1

Indications for Use (Describe)

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Glinical Applicatio | | Mode | ot Operat | 1 | | Color | Combined | - 1 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 |
|---------------------|--|--|--------------|--|-----|----------------------|--|--|
| General | Specific (Track I & III) | . в | M | PWD ² | CWD | Doppler ³ | Modes ⁴ | Other ^{3,8} |
| (Tracks 1 Only) | Ophthalmic | | + | | | | | |
| Ophthalmic | Fetal | P | P | P | P | P | P | |
| | Abdominal ⁶ | P | P | P | P | P | P | |
| | Intra-operative | + | | | - | | | |
| | (Specify) ⁷ | | | | | | | 1 |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | P | |
| | Pediatric Aux | | - | | | | | |
| | Small Organ (Thyroid, | · · · · · · | | 1 | | | - | ł |
| | Breast, Testes, etc.) | l | | | | | | |
| | Neonatal Cephalic | T | T | | | | | |
| | Adult Cephalic | | | 1 | | | | <u> </u> |
| Fetal Imaging & | Trans-rectal | | | | | | | <u> </u> |
| Other | Trans-vaginal | L | | | | | | |
| | Trans-urethral | | | | | | | |
| | | | 1 | | | Į. | | |
| | Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skei. | | | | ļ | | | |
| | | Р | P | P | 1 | P . | | } . |
| | | ļ- | ļ | | | · · · · · · | | - |
| | Musculo-skel. | | | j | 1 | 1 | | |
| | (Superficial) | | | <u> </u> | - | | | |
| | Intravascular | | - | - | | | | |
| | Other (Specify) | | | | | 1. | | |
| | (3D/4D) | P | P | P | | P | · P | |
| | contrast | | 1 | | | | | |
| | Cardiac Adult | P ¹ | P | P | P | P | P | |
| | Cardiac Adult Aux | \ | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| Cardiac | Cardiac Pediatric Aux | | | | | | | |
| Cardiav | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (specify) 3D/4D | | | | | | <u> </u> | ļ |
| | Other (intra-cardiac)* | | | | | | | ļ |
| | Peripheral Vessel | | | | | | | |
| Peripheral Vessel | Peripheral Vessel Aux | | | | | 1 | | <u></u> |
| Lembucian Acaser | Other (Specify) 3D/4D | "- | | | 1 | | | |
| | =previously cleared by FDA | 710/123 | 2141641 | <u>""</u> | | | - | |

N = new indication; P=previously cleared by FDA 510(k) K141641

Lincludes B-Mode and Harmonic (contrast) imaging (HI)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

8 Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

\$10(k) Number (if known)

Device Name

System: ZS3and z.one_{pro}Ultrasound Systems Transducer: Curvilinear Transducer C6-2

Indications for Use (Describe)

| Clinical Applicatio | | Mode | of Operat | on | · / · / · / · / · / · / · / · / · / · / | 學素體的 | | |
|---------------------------|--|------|--|------------------|---|-------------------------------|--------------------------------|--|
| General (Track I Only) | Specific (Tracks 1 & 3) | В | M | PWD ² | CWD | Color Doppler ³ | Combined Modes ⁴ | Other ^{5, 8} |
| Ophthalmic | Ophthalmic | | | | | | | |
| Оримания | Fetal | P | P | P | | P | P | P ⁵ |
| | Abdominal ⁶ | P | P | P | | P | P | P ⁵ |
| | Intra-operative (Specify) | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic |] | | | | | | - |
| | Pediatric | р | P | P | | P | P | P ⁵ |
| | Small Organ (Thyroid, Breast, Testes, etc.) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| Fetal Imaging & | Adult Cephalic | | <u> </u> | - | | | | |
| Other | Trans-rectal | | | | | | | _ |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | ļ | | - | | | | |
| | Trans-esoph. (non- Card.) | | | | | | | } |
| | Musculo-skel. (Conventional) | | | | | | | |
| | Musculo-skel. (Superficial) | | | | | 1 1 | , | ļ |
| | Intravascular | | <u> </u> | | | | | ļ |
| | Other (Specify) (3D/4D) | | | | | | <u> </u> | |
| | Cardiac Adult | | | | | | | ļ |
| | Cardiac Pediatric | | | | | | | - |
| O-utt | Intravascular (Cardiac) | | | | | | | |
| Cardiac | Trans-esoph. (Cardiac) | | | | | | | - |
| | Intra-cardiac | | | | | | | - |
| | Other (Specify) | | <u> </u> | | | | | P ⁵ |
| Po 1 51371 | Peripheral Vascular | P | P | P | | P | P | 1 12- |
| Peripheral Vessel | Other (Specify) | | | | | <u> </u> | <u> </u> | .l <u></u> |

N = new indication; P=previously cleared by FDA 510(k) K141641
Includes B-Mode and Harmonic (contrast) imaging (HI)

includes B-Mode and Harmonic (contrast) imaging (P1)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

§10(k) Number (if known)

Unknown

Device Name

System: ZS3 and z.oneproUltrasound Systems Transducer: Curvilinear Transducer C9-3

Indications for Use (Describe)

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Applicatio | | Mode | of Operat | ipue 💮 | 國國門條 | 38.17.09 - 25 | | 48.005.44.X |
|---------------------|--|------|-----------|------------------|------|------------------|-------------------|-----------------------|
| General | Specific | В | М | PWD ² | CWD | Color Doppler | Combined Modes | Other ^{5, 8} |
| (Track I Only) | (Tracks 1 & 3) | | | | | Dobbier | Muddes | - |
| Ophthalmic | Ophthalmic | | 1 | | | B | P | P ⁵ |
| | Fetal | P | P | P | | P | P | P ⁵ |
| | Abdominal ⁶ | P | P | P | | P | P | - |
| | Intra-operative (Abdominal) | P | P | P | | Р | P | P ⁵ |
| | Intra-operative (Vascular) | P | P | P | | Р | P | P ⁵ |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | P | P ⁵ |
| | Small Organ (Thyroid, Breast, Testes, etc.) | | | | | | ,, | |
| | Neonatal Cephalic | | | | | | l | |
| Fetal Imaging & | Adult Cephalic | | | | | | | |
| Other | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non- Card.) | | | | | | | |
| | Musculo-skei, (Conventional) | P | P | P | | P | P | P ⁵ |
| | Musculo-skel. (Superficial) | P | P | Р | | P | P | P ⁵ |
| | Intravascular | | | | | | | |
| | Other (Specify) (3D/4D) | | | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular (Cardiac) | | | | | | <u> </u> | |
| Cardiac | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Specify) | | | | | | | <u> </u> |
| | Peripheral Vascular | P | P | P | | P | P | P ⁵ |
| Peripheral Vessel | Other (Specify) | | | | | | <u> </u> | |

N = new indication; P=previously cleared by PDA 510(k) K141641

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Includes B-Mode and Harmonic (contrast) imaging (HI)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

Color M-Mode (CM)

Abdominal includes renal, GYN/Pelvic

Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁴ Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3and z.one_{pro}Ultrasound Systems Transducer: Phased (Sector) Array Transducer C10-3

Indications for Use (Describe)

| Citnical Application General | Specific | В | М | PWD ² | CWD | | Combined Modes ⁴ | Other ^{5,1} |
|------------------------------|--|---------------------|--|------------------|--|--|--------------------------------|----------------------|
| (Track I) | (Tracks I & III) | | 141 | | 0112 | Doppler ³ | Modes. | |
| Ophthalmic | Ophthalmic | P | | P | | P | P | p5 |
| | Fetal | P | P | P | P | P | | P ⁵ |
| | Abdominal ⁶ | P | P | P | P | P | P | P ⁵ |
| | Intra-operative (specify) | P | P | P | 1 | P | P | P ⁵ |
| | Intra-operative (Neuro) | P | P | P | ļ., | Р | P | - L |
| | Laparoscopic | | | | | <u> </u> | D | P ⁵ |
| | Pediatric | P | P | P | P | P | P | + |
| | Small Organ (Thyroid, | | | | | 1 | | |
| | Breast, Testes, etc.) | | | | | | P | P ³ |
| | Neonatal Cephalic | P | P | P | P | P | F | |
| | Adult Cephalic/ trans | P. | P | P | P | P | P | P ⁵ |
| Fetal Imaging & | cranial | | ļ <u> </u> | | | - | | + |
| Other | Trans-rectal | | | | | | | |
| | Trans-vaginal | ļ | | | | - | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non- | | | | | 1 | | |
| | Card.) | | | - | | _ | | |
| | Musculo-skel. | | 1 | | | | | - |
| | (Conventional) | | | | | | 1 | |
| | Musculo-skel. | | 1 | | | ļ | | |
| | (Superficial) | | | | | - | | |
| | Intravascular | - | | | | 1 | - | |
| <u> </u> | Other (Specify) | - | P | P | P | P | Р | P ⁵ |
| | Cardiac Adult | P | P | P | P | P | P | P ⁵ |
| | Cardiac Pediatric | P | P | P | F | 1. | 1 | - |
| | Intravascular (Cardiac) | ! | ļ | | | | | |
| Cardiac | Trans-esoph, (Cardiac) | | - | | | | | |
| | Intra-cardiac | | | | | | | - |
| | Other (Specify) | | 1 | | | 1 | , | |
| | (3D/4D) | | P | P. | P | P | P | P ⁵ |
| Davinharal Massal | Peripheral Vascular | P | 1 12 | P. | F | | 1 | |
| | Other (Specify) 3D/4D | <u> </u> | | | <u> </u> | <u>.L</u> | · | |
| Includes B-Mode and | Other (Specify) 3D/4D -previously cleared by the F il Harmonic (contrast) imaging and High Pulse Re | ng (HI) metition | Rate PWD | -Mode (HP | RF) | | | 1,,, |
| | ler (CD), Directional Power FCM, M+CM, B+CD+M+C | Donnler | (INDIN an | a Paurer i R | annier (Pl.) | nt (CD, DPD, Pl | D, or BD) | |

⁶ Abdominal includes renal, GYN/Pelvic

Intra operative include abdominal, thoracic (cardiae) and vascular (PV)

⁸ Freehand tissue elasticity

--Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3 and z.one pro Ultrasound Systems Transducer: Curvilinear Transducer C8-3 (3D)

Indications for Use (Describe)

| Cunical Application | | Mode | of Operat | on was | | | Combined | |
|---|---|----------------------|---------------|------------------|---------------------------------------|-------------------------------|--|-----------------------|
| General | Specific | В | М | PWD ² | CWD | Color Doppler ³ | Modes ⁴ | Other ^{5, B} |
| (Track 1) | (Tracks 1 & 3) | | | | | торрист | IVADGES | |
| Ophthalmic | Ophthalmic | | - | P | | P | P | P ⁵ |
| | Fetal | P | P | P | | P | P | P ⁵ |
| | Abdominal ⁶ | P | P | P | | r_ | <u> </u> | 1 |
| | Intra-operative | | | | | | | |
| | (Specify) | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | P | | P | P | p3 |
| | Pediatric | P | P | P | | F | · · · · · · · · · · · · · · · · · · · | - |
| | Small Organ (Thyroid, | | | | | | | 1 |
| | Breast, Testes, etc.) | | ļ | | | | | |
| | Neonatal Cephalic | | - | ļ | | | **** | |
| Fetal Imaging & | Adult Cephalic | | | | | | | - |
| Other | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | - | | | | |
| | Trans-urethral | | | - | | | | |
| | Trans-esoph. (non- | | 1 | 1 | | | | |
| | Card.) | | | | | | | |
| | Musculo-skel. | | | | | | 1 | |
| | (Conventional) | | | | · · · · · · · · · · · · · · · · · · · | | | - |
| | Musculo-skel. | | | | l | | · ' | |
| | (Superficial) | | + | | | | | |
| | Intravascular | - | P | P | | P | Р | P ⁵ |
| | Other (Specify) (3D/4D) | P | P | P | | | 1 | |
| | Cardiac Adult | | | | - | | | |
| | Cardiac Pediatric | | - | | | | | |
| Cardiac | Intravascular (Cardiac) | | | - | | | | |
| Cardiac | Trens-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | ↓ | | | | | |
| | Other (Specify) | | | _ | | P | P | P ⁵ |
| D 11 (771 | Peripheral Vascular | P | P | P | | Г | F | 1 |
| Peripheral Vessel | Other (Specify) | l | | | <u></u> | | | |
| Includes B-Mode an Includes PWD-Mod Includes Color Dop Includes B+M, B+N Color M-Mode (CM | Pepreviously cleared by FDA de Harmonic (contrast) imaging imaging and High Pulse Replet (CD), Directional Power 4+CM, M+CM, B+CD+M+CD) | ng (HI) epetition | Rate PWD | | | í (CD, DPD, Pi | O, or BD) | |
| Abdominal includes | renal, GYN/Pelvic | | | | | | | |

⁶ Abdominal includes renal, GYN/Pelvic

Intra operative include abdominal, thoracic (cardiae) and vascular (PV)

⁸ Preehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3 and z.onepro Ultrasound Systems

Transducer: Phase (Sector) Array Transducer P4-1c

Indications for Use (Describe)

| General | on Specific | 1 3 37 4 7 7 7 | | | | Color | Combined | Othe |
|---|---|--|-----------|------------------|--|----------------------|--|--|
| (Track I Only) | (Tracks 1 & 3) | B | M | PWD ² | CWD | Doppler ³ | Modes ⁴ | В |
| Ophthalmic | Ophthalmic | 1 | 1 | | | | | |
| Opiniamic | Fetal | P | P | P | Р | P | P | P ³ . |
| | Abdominal ⁶ | P | P | P | P | P | P | P ⁵ |
| | Intra-operative | 1 | + | + | | - | | |
| | (Specify) ⁷ | ļ | ļ | ,,,,, | | | | 4 |
| | Intra-operative (Neuro) | | | | · · | | | - |
| | Laparoscopic | | | | | ļ <u></u> | | P ⁵ |
| | Pediatric | P | P | P | P | P | P | P |
| | Small Organ (Thyroid, Breast, Testes, etc.) | | | | | | | |
| | Neonatal Cephalic | P | P | P | P | P | P | P ⁵ |
| Fetal Imaging & | Adult Cephalic/ trans | P | P | P | P | P | P | P ⁵ |
| Other | Trans-rectal | - | + | - | | | <u> </u> | + |
| | | | | | | - | | + |
| | Trans-vaginal Trans-urethral | | + | ļ | - | | | + |
| | | - | | _ | - | - | | |
| | Trans-esoph. (non- Card.) | | | | | | | |
| | Musculo-skel. | | | | | 1 | | |
| | (Conventional) | | | - 1 | | | | |
| | Musculo-skel. | | 1 | | | | 1 | |
| | (Superficial) | ļ | - | | | | | - |
| | Intravascular | | | | | | | + |
| | Other (Specify) | | | | | <u> </u> | | P ⁵ |
| | Cardiac Adult | P ¹ | P | P | P | P | P | P ⁵ |
| | Cardiac Pediatric | P | P | P | P | P | P | P" |
| | Intravascular (Cardiac) | | 1 | | | | | |
| Cardiac | Trans-esoph, (Cardiac) | | | | | | | |
| | Intra-cardiac | | <u> </u> | | | | | - |
| | Other (Specify) (3D/4D)contrast | P | P | P | | P | P | P ⁵ |
| | Peripheral Vascular | P | P | P | P | P | P | Ps |
| Peripheral Vessel | Other (Specify) | | | | | | <u> </u> | |
| ncludes B-Mode an ncludes PWD-Mode ncludes Calor Donn | previously cleared by the Fl d Harmonic (contrast) imaging e imaging and High Pulse Re- pler (CD), Directional Power (+CM, M+CM, B+CD+M+C | ig (HI) petition R Donnler (| tate PWD- | Mode (HPF | onter (PD) | (CD, DPD, PD | , or BD) | |

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiae) and vascular (PV)

Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3and z.oneproUltrasound Systems

Transducer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Model #V11-3BE Transducer (off-the-shelf) (Endo-Cavity Transducer E9-3)

Indications for Use (Describe)

| Cimical Application | | Mode | of Operat | ión | | | | |
|---------------------------|--|--|--|--|--------------|-------------------------------|--|-----------------------|
| General (Track I Only) | Specific (Track I & III) | В | · M | PWD² | CWD | Color Doppler ³ | Modes ⁴ | Other ^{5, 8} |
| Ophthalmic | Ophthalmic | | | | | | | P ⁵ |
| | Fetal | P | P | P | | P | Ρ | P |
| | Abdominal | | | | | | PPP | |
| | Intra-operative | | | | | i | 1 | |
| | (Specify) ⁷ | | | | | | | |
| | Intra-operative (Neuro) | | | | | | <u> </u> | - |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Thyroid, | ļ | ĺ | | | | 1 | |
| | Breast, Testes, etc.) | | | ļ | | | - | + |
| | Neonatal Cephalic | | | | | | | |
| General | Adult Cephalic | | | | | P | h | P ⁵ |
| application | Trans-rectal | P | P | P | | ~ | | P5 |
| apphoacion | Trans-yaginal | P | P | P | | P | F | F |
| • | Trans-urethral | | | | | | | |
| | Trans-esoph, (non- | | | | | | 1 | |
| | Card.) | | | - | | | - | |
| | Musculo-skel. | | 1 | | | | | |
| | (Conventional) | | | | | | | · · |
| | Musculo-skel. | ! | | | | | | |
| | (Superficial) | - | | | | _ | * | |
| | Intravascular | ļ | - | | | | | |
| | Other (Specify) | l l | | | | | | |
| | (3D/4D) | | | - | | | | <u> </u> |
| | Cardiac Adult | ļ | | | | | | |
| | Cardiac Pediatric | | | | | | <u>-</u> | |
| Cardiac | Intravascular (Cardiac) | - | - | | | | | |
| O | Trans-esoph. (Cardiac) | - | | - | | | - | |
| | Intra-cardiac | | | - | | | - | |
| | Other (Specify) | | | - | | | | |
| Peripheral vascular | Peripheral vascular | | | _ | | | | - |
| • | Other (Specify) | | | _L | <u> </u> | 1 | | <u> </u> |
| I = new indication; P | previously cleared by FDA | 510(k) | K141641 | | | | | |
| Tuningland D. Mode on | d Marmonic (confrast) lift99 | mg (HIII | | Mode CID | DE) | | | |
| Includes PWD-Mode | e imaging and High Pulse R | epetition | KATE PWL | o-IVIOGO (FIP. | nnier (PFN | - | | |
| Includes Color Dopp | oler (CD), Directional Power (+CM, M+CM, B+CD+M+C | ON BYC | י רועוס⊥טי. י רועוס⊥טי | where CD or | uld represen | t (CD. DPD. P | D. or BD) | |
| Includes B+M, B+M | ITUM, MTCM, BTCDTMT | با√ال الالال | ו שבוצו יבו קב | LIMATO OF OF | MAN TANKARAN | (5,, | _,, | |
| Color M-Mode (CM | J manual GN/NI/Delvric | | | | | | | |
| Abdominal includes | Tenni, GY IV/Pervic | | 1am d | NT 21 | | | | |

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3 and z.oneproUltrasound Systems Transducer: Endo-Cavity Transducer E9-4

Indications for Use (Describe)

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Applicatio | | Mode | or Obera | 10年後 料金の | | Color | Combined | and tal-in |
|---------------------------|--|----------|----------|------------------|-----|----------------------|--------------------|-----------------------|
| General (Track 1 Only) | (Tracks 1 & 3) | В | М | PWD ² | CWD | Doppler ³ | Modes ⁴ | Other ^{5, 5} |
| Ophthalmic | Ophthalmic | | | | | | ļ | P ⁵ |
| | Fetal | P | P | P | | P | P | P |
| | Abdominal | | | | | | | ├ |
| | Intra-operative (Specify) ⁷ | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | ļ |
| | Laparoscopic | | | | | | | |
| | Pediatrio | | | | | | ļ | - |
| | Small Organ (Thyroid, Breast, Testes, etc.) | | | | | | | ļ |
| | Neonatal Caphalic | | | | | | | |
| Estal Turneling Pr | Adult Cephalic | | | | | | <u> </u> | P ⁵ |
| Fetal Imaging & Other | Trans-rectal | Ρ, | P | P | | P | P | P ⁵ |
| Offici | Trans-vaginal | P | P | P | | P | P | P P |
| | Trans-urethral | <u>L</u> | | | | | _ | |
| | Trans-esoph, (non- | | i | | | | | |
| | Card.) | | - | | | | - | - |
| | Musculo-skel. | | | | | | | 1 |
| | (Conventional) | | | | | | - | |
| | Musculo-skel. (Superficial) | | | | | | | |
| | Intravascular | ļ | | | | | | - |
| | Other (Specify) (3D/4D) | | | | | | | |
| | Cardiac Adult | | | | | <u> </u> | | |
| | Cardiac Pediatric | | | | | | | |
| Chudlan | Intravascular (Cardiac) | | | | | | | |
| Cardiac | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-Cardiac | | | ļ | | | ļ | |
| | Other (Specify) | | | | | | | - |
| D 11 - 131 - 1 | Peripheral vascular | | | | | ļ | | |
| Peripheral Vessel | Other (Specify) | | | | | | | L., |

N = new indication; P=previously cleared by FDA 510(k) K141641



FORM FDA 3881 (8/14)

Includes B-Mode and Harmonic (contrast) imaging (HI)

Includes PWD-Mode imaging and High Fulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3and z.oneproUltrasound Systems Transducer: Endo-Cavity Transducer E9-3 (3D)

Indications for Use (Describe)

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Childal Application | | Mode | of Operat | ion is sign | e na na na | Color | Combined | in Page |
|--------------------------|---|-------------|--------------|------------------|--------------|----------------------|--|--|
| General | Specific- | В | М | PWD ² | CWD | Doppler ³ | Modes ⁴ | Other5, |
| (Track 1 Only) | (Tracks 1 & 3) | | | | | Dobbier | MICGOS | + |
| Ophthalmic | Ophthalmic | ļ | | 15 | | P | P | P5 |
| | Fetal | P | P | P | | . P. | <u> </u> | + |
| | Abdominal | ļ | ļ | | | | | + |
| | Intra-operative (Specify) ⁷ | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | - |
| | Laparoscopic | | | | | | | - |
| | Pediatric | | | | | | | <u> </u> |
| | Small Organ (Thyroid, | | | | | | | |
| | Breast, Testes, etc.) | | | | | | | |
| | Neonatal Cephalic | | | | | | <u> </u> | ļ |
| | Adult Cephalic | | 1 | | | | | p ⁵ |
| Fetal Imaging & | Trans-rectal | P | P | P | | P | P | |
| Other | Trans-vaginal | P | P | P | | P | P | P ⁵ |
| | Trans-urethral | | | | | | · | - |
| | Trans-esoph. (non- | | |] | [| | 1 | |
| | Card.) | | | | | | | - |
| | Musculo-skel, | | | | | 1 | i | |
| | (Conventional) | 1 | | | | | | |
| | Musculo-skel. | | | | | | ' | |
| | (Superficial) | | | <u> </u> | | | | |
| | Intravascular | | | | | | | - |
| | Other (Specify) | Р | P | P | | P | P | P5 |
| | (3D/4D) | F | 1 | 1 | | | | |
| | Cardiac Adult | l | <u> </u> | | | <u> </u> | |) |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular (Cardiac) | 1 | T | | | <u> </u> | | |
| Cardiac | Trans-esoph, (Cardiac) | | | <u> </u> | | | | ļ |
| | Intra-cardiac | | | | | | | - |
| | Other (Specify) | | | | | <u> </u> | | - |
| | Peripheral vascular | 1 | | | | | ļ.——— | ļ |
| Peripheral Vessel | Other (Specify) | | | Ī | | <u> </u> | | |
| I m more indigation: D | previously cleared by FD/ | 510(k) F | C141641 | | | | | |
| To alander D. Mode on | d Harmonie (contract) imag | ing (HII) | | | | | | |
| To dead on DIETTS & fold | a imaging and High Pulse R | enctifion | Rate PWD | -Mode (HP | RF) | | | |
| | | | | | | | | |
| Includes B+M. B+N | HCM, M+CM, B+CD+M+ | CM, B+C | D+PWD v | yhere CD co | uld represer | ıt (CD, DPD, P | D, or BD) | |
| Color M-Mode (CM | n í | • | | | | | | |

11 OF 21

⁵ Color M-Mode (CM)

⁶ Abdominat includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiae) and vascular (PV)

⁸ Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3 and z.one pro Ultrasound Systems Transducer: Linear Transducer L10-5

Indications for Use (Describe)

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | ner en | Mode | of Operat | ion 1888 | | | | |
|----------------------|--|--------------|--|------------------|-----|----------------------|--------------------------------|----------------------------------|
| General | Specific | В | M | PWD ² | CWD | I Color | Combined Modes ⁴ | Other ^{5, 8} |
| (Track I Only) | (Tracks 1 & 3) | | 171 | | | Doppler ³ | | ļ |
| Ophthalmic | Ophthalmic | P | | P | | P | P | p ⁵ |
| | Fetal | P | P | P | | P | P | P ⁵ |
| | Ahdominal ⁶ | ₽ | P | P | | P | P | _ |
| | Intra-operative (Specify) ⁷ | P | P | P | | P | P | P ⁵ |
| | Intra-operative (Neuro) | P | | P | | P | P | Ď2 |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | P | P ⁵ |
| | Small Organ (Thyroid, Breast, Testes, etc.) | P | P | P | | P | P | P ⁵ P ⁸ |
| | Neonatal Cephalic | P | P | P | | P | P | P ⁵ |
| | Adult Cephalic | <u> </u> | 1 | | | | | |
| Petal Imaging & | Trans-rectai | | | | | | | |
| Other | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | - | | | | |
| | Trans-esoph, (non- | | | | | | | |
| | Card.) Musculo-skel. (Conventional) | p | P | P | | P | Р | P ^{5, 8} |
| | Musculo-skel. (Superficial) | P | P | P | | Р | Р | P ^{5, 8} |
| | Intravascular | | | | | | | |
| | Other (Specify) ⁸ (3D/4D) | | | | | | | |
| | Cardiac Adult | | <u> </u> | | | | l | |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | |
| Cardiac | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Specify) | - | 1 | | | | | |
| | Peripheral Vascular | P | P | P | | P | Р | P ^s P ^s |
| Peripheral Vessel | Other (Specify) 3D/4D | | | | | | <u></u> | |

N = new indication; P=previously cleared by the FDA 510(k) K141641
Includes B-Mode and Harmonic (contrast) imaging (HI)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

B Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3 and z.oneproUltrasound Systems

Transducer: Linear Transducer L8-3

Indications for Use (Describe)

| ic s 1 & 3) almic ninal ⁶ operative (fy) ⁷ operative (Neuro) oscopic ric Organ (Thyroid, | P P P | P P | PWD ² P P | CWD | Color Doppler ³ P P | Combined Modes ⁴ | P ⁵ |
|---|---|--|--|--------------------------------------|--|--|-------------------------------------|
| almic minal ⁶ operative fy) ⁷ operative (Neuro) oscopic ric Organ (Thyroid, | P P | P | P P | | p P | P P | P ⁵ |
| ninal ⁶ pperative fy) ⁷ pperative (Neuro) oscopie tric Organ (Thyroid, | P P | P | P P | | P | P | P ⁵ |
| operative (Neuro) oscopic oric Organ (Thyroid, | P P | P | P P | | P | P | P ⁵ |
| operative (Neuro) oscopic oric Organ (Thyroid, | P P | | P | | · | | _ (|
| riy) ⁷ operative (Neuro) oscopic oric Organ (Thyroid, | P | P |]] | | P | l D | |
| oscopic ric Organ (Thyroid, | | | | | | <u> </u> | P ⁵ |
| ric Organ (Thyroid, | | | P | | P | P | F |
| Organ (Thyroid, | | | | | | | P5 |
| Organ (Thyroid, | P | P | P | | P | P | P p5 |
| i. 103103, 010.) | P | P | P | | P | P | P ⁸ |
| tal Cephalic | P | P | P | | P | P | P ⁵ |
| Cephalic | | | | | ` | <u> </u> | - |
| -rectal | | | | | | | |
| -vaginal | | | | | | | |
| | | | | | | | |
| -esoph. (non- | | | | | | | |
| Musculo-skel. (Conventional) | P | P | P | | P | P | P ^{5, 8} |
| ulo-skel. | P | P | P | | Р | P | P ^{5, 8} |
| | | | | | | | |
| (Specify) ⁸ | | | | | | | |
| | - | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | ļ |
| | | | | | | | |
| | P | P | P | | P | P | P ⁵ |
| | | | | | | <u> </u> | |
| | ventional) ulo-skel. rificial) vascular (Specify) ac Adult ac Pediatric vascular (Cardiac) cardiac (Specify) heral Vascular (Specify) Cypecify) Cypecify) Cypecify) Cypecify) Cypecify) | -urethral -csoph. (non-) ulo-skel. ventional) ulo-skel. porticial) vascular (Specify) ⁸ D ac Adult ac Pediatric vascular (Cardiac) -csoph. (Cardiac) cardiac (Specify) heral Vascular (Specify) D coric (contract) imaging (HD) | -urethral -csoph. (non-) ulo-skel. P P ventional) ulo-skel. P P reficial) vascular (Specify) ⁸ D ac Adult ac Pediatric vascular (Cardiac) -csoph. (Cardiac) -cardiac (Specify) heral Vascular P CSpecify) D usly cleared by the FDA 510(k) K1416 | -urethral -csoph. (non-)) ulo-skel. | -urethral -csoph. (non-) ulo-skel. P P P ulo-skel. P P P ulo-skel. P P P vascular (Specify) ⁸ D ac Adult ac Pediatric vascular (Cardiac) -csoph. (Cardiac) | -urethral -csoph. (non-)) ulo-skel. P P P P ulo-skel. P P P P pertional) ulo-skel. P P P P refficial) rescular (Specify) ⁸ D ac Adult ac Pediatric rescular (Cardiac) -csoph. (Cardiac) | -urethral -esoph. (non-) ulo-skel. |

⁸ Freehand tissue elasticity



⁶ Abdominal includes renal, GYN/Pelvic

² Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3 and z.onepro Ultrasound Systems Transducer: Linear Transducer L14-5sp

Indications for Use (Describe)

| Clinical Applicatio | in Carlotte | Mode | of Opera | lon are | | | 并明制制度的 | |
|---------------------|---|------|----------|--|-----|----------------------|--------------------|----------------------------------|
| General | Specific | В | М | PWD ² | CWD | COLOR | Combined | Other ^{5, 8} |
| (Track I Only) | (Track 1 & 3) | | 141 | | CHE | Doppler ³ | Modes ⁴ | |
| Ophthalmic | Ophthalmic | P | | P | | P | P | - p ⁵ |
| | Fetal | P | P | P | | P | P | P ⁵ |
| | Abdominal ⁶ | P | P | P | | P | P | P" |
| | Intra-operative (Specify) ⁷ | p | P | P | | P | P | P.5 |
| | Intra-operative (Neuro) | P | | P | | P | Р | P ⁵ |
| | Laparoscopic | | <u> </u> | | | | <u> </u> | |
| | Pediatric | P | P | P | | P | P | P ⁵ |
| | Small Organ (Thyroid, Breast, Testes, etc.) | P | P | P | | P | P | P ⁵ |
| | Neonatal Cephalic | P | P | P | | P | P | P ⁵ |
| | Adult Cephalic | | | i | | | | |
| Petal Imaging & | Trans-rectal | | | | | | | |
| Other | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non- Card.) Musculo-skel. (Conventional) | | | | | | | |
| | | P | P | Р | | Р | P | P ^{5, 8} |
| | Musculo-skel. (Superficial) | P | P | P | | P | P | P ^{5, 8} |
| | Intravascular | | | | | | | |
| | Other (Specify) ⁸ 3D/4D | | | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | ↓ |
| | Intravascular (Cardiac) | 1 | | | | | | |
| Cardiac | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Specify) | | | | | | | |
| | Peripheral Vascular | P | Р | Р | | P | P | P ⁵ P ⁸ |
| Peripheral Vessel | Other (Specify) 3D/4D | | | | | | | <u>.</u> :- |

N = new indication; P=previously cleared by the FDA 510(k) K141641

Includes B-Mode and Harmonic (contrast) imaging (HI)
Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, FD, or BD)

Color M Mode (CD)

Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3and z.one_{pro}Ultrasound Systems Transducer: Linear Transducer L14-5w

Indications for Use (Describe)

| Track 1 Only) Ophthalmic | Specific | | | | | Color | Combined | 0.0.5 |
|------------------------------|--|--------------|-----------|------------------|-----|----------------------|--------------------|----------------------------------|
| Ophthalmic | (Tracks 1 & 3) | В | M | PWD ² | CWD | Doppler ³ | Modes ⁴ | Other ⁵ |
| | Ophthalmic | P | | P | | P | P | - |
| | Fetal | P | P | P | | P | P | P ³ |
| Γ | Abdominal ⁶ | P | P | P | | P | P | P ⁵ |
| | Intra-operative (Specify) ⁷ | P | P | P | | P | P | P ⁵ |
| | Intra-operative (Neuro) | P | | P | | P | P | P ⁵ |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | P | P ⁵ |
| | Small Organ (Thyroid, Breast, Testes, etc.) | P | P | P | | P | P | P ⁵ P ⁸ |
| | Negnatal Cephalic | P | P | P | | P | P | P ⁵ |
| F- | Adult Cenhalic | | | | | | | Ĺ |
| Fetal Imaging & 📑 | Trans-rectal | | | | | | | |
| liner | Trans-vaginal | | | | | | | |
| | Trans-urethral | | · · | | | | | |
| | Trans-esoph. (non- | | | 1 | | | | |
| | Card.) | | 1 | | | | <u> </u> | |
| Musculo-skel. (Conventional) | P | P | P | | P | Р | P5, 8 | |
| | Musculo-skei. (Superficial) | P | P | P | | P | P | P ^{5, 8} |
| | Intravascular (Cardiac) | | | | | | | |
| | Other (Specify) ⁸ 3D/4D | | | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| <u> </u> | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Specify) | | | | | | | |
| | Peripheral Vascular | P | P | P | | P | P | P ⁵ |
| Peripheral Vessel | Other (Specify) 3D/4D | | k) K14164 | | · | | <u> </u> | |



⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue clasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

)0(k) Number (if known)

Device Name

System: ZS3and z.one_{pro}Ultrasound Systems Transducer: Linear Transducer L20-5

Indications for Use (Describe)

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Specify)? F Specify)? F Neuro) F syroid, F ic F sn-Card.) F Superficial) F | | P P P P | PWD² P P P P P P P | CWD | Doppler ³ P P P P P P P P P | Modes ⁴ P P P P P P P | P5 P |
|--|--|---|--|--|---|---|---|
| Specify) P Specify) P Neuro) F yroid, F ic.) F on-Card.) | | P P P P | P P P P P | | P P P P | P P P P P | P ⁵ |
| Specify) ⁷ P Neuro) P yroid, (c.) ic P on-Card.) | | P P P P | P P P P | | P P P P | P P P P | P ⁵ |
| Specify) P Neuro) P yroid, (c.) ic F on-Card.) | | P P P P | P P P | | P P P | P P P | P ⁵ P ⁵ P ⁵ P ⁵ P ⁸ P ⁵ |
| Neuro) P Fyroid, F ic.) F on-Card.) P | | P P P | P P P | | P P P | P P P | P ⁵ P ⁵ P ⁸ P ⁵ |
| Neuro) P Fyroid, F ic.) F on-Card.) P | | P | P P | | P P | P P | P ⁵ P ⁵ P ⁵ |
| yroid, F to.) F ic F on-Card.) | | P | P P | | P | P | P ⁵ p ⁸ |
| yroid, F. (c.) F. (c.) ic F. (c.) F. (| | P | P P | | P | P | P ⁵ p ⁸ |
| ic F | | P | P | | P | P | P ⁸ |
| ic F | | P | P | | P | P | P ⁵ |
| n-Card.) | | P | | | | | |
| P | | <u> </u> | P | | P | P | Ď2' g |
| P | | <u> </u> | P | | P | P | P ₂ ′ g |
| P | | <u> </u> | p | | P | P | P ^{5, 8} |
| P | | <u> </u> | P | | P | P | P ^{5, 8} |
| P | | <u> </u> | P | | P | P | P ^{5, 8} |
| P | | <u> </u> | Р | | P | P | P ^{5, 8} |
| | | <u> </u> | " | | 1 A | 1 * | 1 * |
| uperficial) P | ` | | | | | | |
| | | P | P | | P | P | P ^{5, 8} |
| | | | | | | | |
| | | | 1 | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | - | | | | Ť |
| | | | | | | | |
| R(UIAC) | | | 1 | | | | |
| | | | | | | | |
| ılar F | , | P | P | | P | P | P ⁵ |
| | | | | | | | |
| | rdiac) rdiac) far I by the FDA 5 st) imaging (H Pulse Reporter | rdiac) rdiac) lar P by the FDA 510(k) I st) imaging (HI) Pulse Repetition Rat | rdiac) rdiac) far P P by the FDA 510(k) K141641 st) imaging (HI) Pulse Repetition Rate PWD-N and Bower Donnier (DPD) and | rdiac) rdiac) far P P P by the FDA 510(k) K141641 st) imaging (HI) Pulse Repetition Rate PWD-Mode (HPRF) all Rouge Donnler (UPD) and Power Donnler | rdiac) rdiac) far P P P by the FDA 510(k) K141641 st) imaging (HI) Pulse Repetition Rate PWD-Mode (HPRF) and Power Donnler (PDI) and Power Donnler (PD) | rdiac) rdiac) far P P P P by the FDA 510(k) K141641 st) imaging (HI) Pulse Repetition Rate PWD-Mode (HPRF) and Power Donnler (PD) | rdiac) rdiac) far P P P P P by the FDA 510(k) K141641 st) imaging (HI) Pulse Renefition Rate PWD-Mode (HPRF) |

16 OF 21

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

^B Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3and z.oneproUltrasound Systems

Transducer: Tran-Esophageal Transducer: P8-3TEE

Indications for Use (Describe)

| Clinical Application | 11 | Mode | of Operat | ion | | | I combined | |
|---------------------------|--|--|----------------------|--|---------------|-------------------------------|--------------------------------|--|
| General (Track 1 Only) | Specific (Tracks I & 3) | В | M | PWD ² | CWD | Color Doppler ³ | Combined Modes ⁴ | Other5, |
| Onhthalmic | Ophthalmic | | + | <u> </u> | | | | |
| Opninamic | Fetal | - | + | | | | | |
| | Abdominal | | - | | | | | |
| | Intra-operative | | 1 | | | | | 1 |
| | (Specify) ⁷ | | | | _ | | | |
| | Intra-operative (Neuro) | | 1 | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | " | | | | | |
| | Small Organ (Thyroid, | | | | | | | ĺ |
| | Breast, Testes, etc.) | 1 | | <u> </u> | | | | <u> </u> |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| Fetal Imaging & | Trans-rectal | | | | | | | |
| Other · | Trans-vaginal | | | | | | | <u> </u> |
| | Trans-urethral | | | | | | | |
| | Trans-esoph, (non- | P | P | P | Р | P | P | P5 |
| | Card.) | I. | 1 | <u> </u> | | | ļ | |
| | Musculo-skel. | | Į. | | | | 1 | |
| | (Conventional) | | | | | | | - |
| | Musculo-skel. | | | | | | 1 | |
| | (Superficial) | | - | - | | | | |
| | Intravascular | | | | | | | |
| | Other (Specify) | | | | | ŀ | | |
| | (3D/4D) | | - | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | _ | | | | |
| Cardiac | Intravascular (Cardiac) | P | P | P | P | Р | Р | P5 |
| CAL DILLO | Trans-esoph. (Cardiac) | P | F | F | F | | - | |
| | Intra-cardiac | | | | - | | | |
| | Other (Specify) | | | | | <u> </u> | | |
| Peripheral Vessel | Peripheral Vessel | | | | - | | | - |
| - | Other (Specify) | <u> </u> | | | <u> </u> | ! <u></u> | <u> </u> | <u> </u> |
| = new indication; I | previously cleared by FDA | 510(k) F | (141641 | | | | | |
| Includes B-Mode or | id Harmonic (contrast) imagi | ing (Hil) | | Mode (UD) | DE) | | • | |
| Includes PWD-Mod | e imaging and High Pulse R | epetition. | VDDD) == | -Mouver D | nnler (PD) | | | |
| Includes Color Dop | pler (CD), Directional Power M+CM, M+CM, B+CD+M+C | OW BTU | U+bMU a (ntn)' ar | where CD or | oppler (12) | t (CD. DPD. PI | O, or BD) | |
| includes B+M, B+N | ATCIVI, IVITCIVI, DTCDTIVITO O | CIAT ² D.L.C. | TALLY KATTA A | TAINEN WAS WE | and tally and | | -, | |
| Color M-Mode (CM | i renal, GYN/Pelvic | | | | | | | |



⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Prechand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (If known)

Device Name

System: ZS3and z.oneproUltrasound Systems

Transducer: St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005 (off the shelf) (P9-3ic)

Indications for Use (Describe)

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical/Application | | Mode | of Operati | lon . | | | | APPLE CONDICATIONS |
|--|--|--|--|--------------|--------------------|-------------------------------|--------------------------------|----------------------|
| General | Specific | l B | м | PWD^2 | CWD | Color Doppler ³ | Combined Modes ⁴ | Other ^{3,8} |
| (Track 1 Only) | (Tracks I & 3) | | | | | Doppier | Modes | ļ |
| Ophthalmic | Ophthalmic | | | | | | | |
| | Fetal | | | | | <u> </u> | } | - |
| | Abdominal | | ļ | | | | <u> </u> | |
| | Intra-operative (Specify)? | l | | | | | | |
| | Intra-operative (Neuro) | | l | | | | <u> </u> | |
| | Laparoscopic | | | | | <u> </u> | | |
| | Pediatric | 1 | | | | | | |
| | Small Organ (Thyroid, Breast, Testes, etc.) | | | | | | | |
| | Neonatal Cephalic | <u> </u> | | | | | <u> </u> | |
| | Adult Cephalic | 1 | | | Ĩ | · | | |
| Fetal Imaging & | Trans-rectal | | 1 | | | | | |
| Other | Trans-vaginal | | | | · | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph, (non- | | | | | | | |
| | Card.) | l | | | <u> </u> | <u> </u> | <u> </u> | |
| | Musculo-skel, | | | | | | | |
| | (Conventional) | <u> </u> | | | | | | |
| | Musculo-skel. | Ţ | | | | | | |
| | (Superficial) | | | | | | | |
| | Intravascular | | | | | | | |
| | Other (Specify) (3D/4D) | | | | | | | |
| | Cardiac Adult | | - | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | |
| Cardiac | Trans-esoph. (Cardiac) | - | | | | | | |
| | Intra-cardíac | | - | | | | · · | |
| | Other (Specify) | P | P | P | P | P | P | |
| · · · · · · · · · · · · · · · · · · · | Peripheral vascular | | +- | | | · | | |
| Peripheral Vessel | | | 1 | | | | | |
| * | Other (Specify) | 440415 | 1111111 | 4 T. J. 7700 | 1066 B 1707 | 2700 | | L |
| Includes B-Mode and Includes PWD-Mode | =previously cleared by FDA I Harmonic (contrast) imaging and High Pulse R. Ier (CD), Directional Power +CM, M+CM, B+CD+M+C | ing (HI) epetition l Donnler | Rate PWD | -Mode (HP | RF) onnier (PD) | | O. or BD) | |
| Includes B+M, B+M Color M-Mode (CM) | tcivi, Mitcivi, Bitciitiviti I | JIVI, DTW | א ענא צוע | | rand tales anger | 4 (mar) m - m 3 * * | | |

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiae) and vascular (PV)

8 Freehand tissue elasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (If known)

Device Name

System: ZS3 and z.one $_{pro}$ Ultrasound Systems Transducer: A2CW (Common name Pencil Probe)

Indications for Use (Describe)

| General (Track 1 Only) | Clinical Applicatio | n | Mode | of Operat | ion | | | | |
|--|---------------------|-------------------------|----------|-----------|------------------|--------------|---------|----------|-----------------------|
| Cardiac Card | General | Specific | В | М | PWD ² | CWD | Color | Combined | Other ^{5, 8} |
| Fetal Abdominal Intra-operative (Specify)' Intra-operative (Neuro) Laparoscopic Pediatric P P P P P P P P P | | | | | 7 1,72 | | Doppier | Modes | |
| Abdominal Intra-operative (Specify) | Ophthalmic | | | - | | | | | |
| Intra-operative (Specify) | | | | | | | | | - |
| Cardiac Card | | | | | | | | | |
| Intra-operative (Neuro) Laparoscopic Pediatric P | | Intra-operative | | | | l | | | |
| Laparoscopic Pediatrie P | | (Specify) ⁷ | | ļ | | | | | |
| Pediatric P | | | | | | | | | |
| Small Organ (Thyroid, Breast, Testes, etc.) | | | | | | <u> </u> | | | |
| Breast, Testes, etc.) Neonatal Cephalic Adult Cephalic | | | | | | P | | | |
| Neonatal Cephalic Adult Cephalic | | Small Organ (Thyroid, | | 1 | i | | | | |
| Adult Cephalic Trans-rectal Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-soph. (non-Card.) Musculo-skel. (Conventional) Musculo-skel. (Superficial) Intravascular Intra-luminal Other (Specify) (3D/4D) Cardiae Pediatric P Cardiae Pediatric P Cardiae Pediatric Intra-esoph. (Cardiae) Intra-esoph. (Cardiae) Intra-esoph. (Cardiae) Intra-cardiae Other (Intra-Cardiae) Intra-cardiae Intra-cardi | | | <u> </u> | · · | | | | | |
| Trans-rectal Trans-rectal Trans-vaginal Trans-vaginal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Conventional) Musculo-skel. (Superficial) Intravascular Intra-luminal Other (Specify) (3D/4D) Cardiac Adult P Cardiac Adult P Cardiac Pediatric Intra-esoph. (Cardiac) Intra-esoph. (Cardiac) Intra-cardiac Other (Intra-Cardiac) Intra-cardiac | | | | ļ | | ļ | | | |
| Other Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Conventional) (Conventional) Musculo-skel. (Superficial) (Superficial) Intra-luminal Other (Specify) (3D/4D) Cardiac Adult P Cardiac Pediatric P Intravascular (Cardiac) P Intra-csoph. (Cardiac) Intra-cardiac Other (Intra-Cardiac) Other (Intra-Cardiac) | | | <u> </u> | <u> </u> | | | | | |
| Trans-urethral Trans-esoph. (non- Card.) Musculo-skel. (Conventional) Musculo-skel. (Superficial) Intravascular Intra-luminal Other (Specify) (3D/4D) Cardiac Adult Cardiac Pediatric Intravascular P Intravascular P Cardiac Pediatric Intravascular P Intravascular P Intravascular P Cardiac Pediatric Intravascular (Cardiac) Trans-esoph. (Cardiac) Intra-cardiac Other (Intra-Cardiac) | Fetal Imaging & | Trans-rectal | <u> </u> | <u> </u> | | | | | |
| Trans-esoph. (non-Card.) | Other | | | | | | | | |
| Card. Musculo-skel. (Conventional) Musculo-skel. (Superficial) Intravascular Intra-luminal Other (Specify) (3D/4D) Cardiac Adult P Cardiac Pediatric P Intravascular (Cardiac) Intravascular (Cardiac) Intravascular (Cardiac) Intra-cardiac Other (Intra-Cardiac) Other (Intra-Cardiac) Intra-cardiac Other (Intra-Cardiac) Other (Intr | | | | | | | | | |
| Musculo-skel. (Conventional) Musculo-skel. (Superficial) Intravascular Intra-luminal Other (Specify) (3D/4D) Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph, (Cardiac) Intra-cardiac Other (Intra-Cardiac) | | Trans-esoph. (non- | 1 | | | | | | İ |
| (Conventional) Musculo-skel. (Superficial) Intravascular Intra-luminal Other (Specify) (3D/4D) Cardiac Adult Cardiac Pediatric Intra-scoph, (Cardiac) Trans-esoph, (Cardiac) Intra-cardiac Other (Intra-Cardiac) | | | | | | | | | |
| Musculo-skel. (Superficial) Intravascular Intra-luminal Other (Specify) (3D/4D) Cardiac Adult P Cardiac Pediatric P Intravascular (Cardiac) Intra-cardiac Intra-cardiac Other (Intra-Cardiac) Other | | | | | | | ĺ | | |
| (Superficial) Intravascular Intra-luminal Other (Specify) (3D/4D) Cardiac Adult Cardiac Pediatric Intravascular (P Intravascular (Cardiac) Trans-esoph, (Cardiac) Intra-cardiac Other (Intra-Cardiac) | | | | | | | | | |
| Intravascular Intra-luminal Other (Specify) (3D/4D) Cardiac Adult P Cardiac Pediatric P Intravascular (Cardiac) Intra-cardiac Intra-cardiac Other (Intra-Cardiac) Other (I | · | | 1 | 1 | | | | | |
| Intra-luminal | | | | | | | | | |
| Other (Specify) (3D/4D) Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph, (Cardiac) Intra-cardiac Other (Intra-Cardiac) | | | | | | , | | | |
| (3D/4D) Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph, (Cardiac) Intra-cardiac Other (Intra-Cardiac) | | | | | ļ | | | | |
| Cardiac Adult P Cardiac Pediatric P Intravascular (Cardiac) Trans-esoph, (Cardiac) Intra-cardiac Other (Intra-Cardiac) | | | 1 | | | i | | | |
| Cardiac Padiatric P | | | | | | | | | |
| Cardiac Intravascular (Cardiac) Trans-esoph, (Cardiac) Intra-cardiac Other (Intra-Cardiac) | | | <u> </u> | <u> </u> | | | | | |
| Cardiac Trans-esoph, (Cardiac) Intra-cardiac Other (Intra-Cardiac) | | | | | | P | | | |
| Intra-cardiac Other (Intra-Cardiac) | a. B. | Intravascular (Cardiac) | | | | ļ | | | |
| Other (Intra-Cardiac) | Cardiac | | | <u> </u> | | | | | |
| Other (Intra-Cardiac) | | Intra-cardiac | | | | | | | |
| | | Other (Intra-Cardiac) | | | <u> </u> | | | | ļ |
| A WARPING THE STATE OF THE STAT | | Peripheral vascular | | | | | | | |
| Peripheral Vessel Other (Specify) | Peripheral Vessel | | | | | | | | |



N = new indication; P=previously cleared by FDA 510(k) K141641

Includes B-Mode and Harmonic (contrast) imaging (HI)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

Color M Mode (CS)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue clasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3and z.oneproUltrasound Systems Transducer: A5CW (Common name Pencil Probe)

Indications for Use (Describe)

| Clinical Applicatio | Clinical Application | | | lon | | | | |
|--|----------------------------|----------|---|------------------|----------|-------------------------------|--------------------------------|-----------------------|
| General (Track 1 Only) | Specific (Tracks 1 & 3) | В | М | PWD ² | CWD | Color Doppler ³ | Combined Modes ⁴ | Other ^{5, 8} |
| Ophthalmic | Ophthalmic | | | | | | | |
| Оришини | Fetal | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative | | | 1 | | | | |
| | (Specify) ⁷ | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | l | | | <u> </u> | |
| | Pediatric | | | | P | | | |
| | Small Organ (Thyroid, | | | | | | | |
| | Breast, Testes, etc.) | | | <u> </u> | ļ | | | |
| | Neonatal Cephalic | | | | | | | |
| The state of the s | Adult Cephalic | | | | | | | |
| Fetal Imaging & Other | Trans-rectal | | | | | | | |
| Ciner | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | ļ | | | |
| | Trans-esoph, (non- | 1 | | j ' | | | | |
| | Card.) | | | | | | | |
| | Musculo-skel, | į. | l | | | ŀ | | |
| | (Conventional) | <u> </u> | | | | ļ <u> </u> | | |
| | Musculo-skel. | | 1 | | | | | İ |
| | (Superficial) | | | | | | | |
| | Intravascular | | ļ | - | | | | |
| | Other (Specify) | | | | ŀ | } | | 1 |
| | (3D/4D) | | - | | - | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiao Pediatric | | ļ | | | | | |
| Cardiac | Intravascular (Cardiac) | | | ļ | | - | | |
| Catulac | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Intra-Cardiac) | | | | P | | | |
| Designment Mossel | Peripheral vascular | | | <u> </u> | r | 1 | | |
| Peripheral Vessel | Other (Specify) | | | | <u> </u> | l | <u> </u> | l |

N = new indication; P=previously cleared by PDA 510(k) K.141641

Includes B-Mode and Harmonic (contrast) imaging (HI)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Very Report Repor

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic
⁷ Intra operative include abdominal, thoracic (cardiae) and vascular (PV)

⁸ Freehand tissue clasticity

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

0(k) Number (if known)

Device Name

System: ZS3and z.one_{pre}Ultrasound Systems Transducer: Curvilinear Transducer C9-3sp

Indications for Use (Describe)

| | Specific | | 1 | | | Color | Combined | Other ^{5, 1} |
|---------------------------|--|---|----------|--|-----|----------------------|----------|--|
| General (Track I Only) | (Track I & III) | В | M | PWD ² | CWD | Doppier ¹ | Modes⁴ | Other |
| Ophthalmic | Ophthalmic | | | | | | | |
| | Fetal | N | N | N | | N | N | N ⁵ |
| | Abdominal | N | N | N | | N | N | N ³ |
| | Intra-operative (Abdominal) ⁷ | N | N | N | | N | N | N ⁵ |
| | Intra-operative (Vascular) | N | N | N | _ | И | N | N ⁵ |
| | Laparoscopic | | | | | | J | 2.75 |
| | Pediatric | N | N | N | | N | N | N ⁵ |
| | Small Organ (Thyroid, Breast, Testes, etc.) | | | | | | | |
| | Neonatal Cephalic | | | | | | | ļ |
| General | Adult Cephalic | | | | | | | |
| application | Trans-rectal | | | <u> </u> | | | | |
| -71 | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | ļ |
| | Trans-esoph. (non- Card.) | | | | | | | ļ <u> </u> |
| | Musculo-skel. (Conventional) | N | N | N | | N | N | N ⁵ |
| | Musculo-skel. (Superficial) | N | N | N | | N | N | N ⁵ |
| | Intravascular | | | | | | | |
| | Other (Specify) (3D/4D) | | | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | <u> </u> | | | | | |
| C-4- | Intravascular (Cardiac) | | | | | | | |
| Cardiac | Trans-esoph. (Cardiac) | | | <u> </u> | | ļ | | |
| | Intra-cardiac | | | | | | | - |
| | Other (Specify) | | | | | 3: | 3.7 | N ⁵ |
| Danish and magnific | Peripheral vascular | N | N | N | | N | N | IN. |
| Peripheral vascular | Other (Specify) | | | | | | 1 | |

N = new indication; P=previously cleared by FDA 510(k) K141641
Includes B-Mode and Harmonic (contrast) imaging (HI)



Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic 7 Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue clasticity



This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92 510(k).

General Information

| Applicant: | ZONARE Medical Sy | estems, Inc. | | | | | | |
|--------------------|------------------------------------|---|-----------------------|--|--|--|--|--|
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| | E-mail: sgeerdes@zoi | nare.com | | | | | | |
| Date Prepared: | October 21, 2014, 201 | 4 | | | | | | |
| Trade Name(s): | ZS3 Ultrasound Syste | | | | | | | |
| | z.one _{pro} Ultrasound Sy | | | | | | | |
| Common Name: | Diagnostic Ultrasound | Diagnostic Ultrasound System with Accessories | | | | | | |
| Classification: | II | | | | | | | |
| Classification | Ultrasonic Pulsed | Ultrasonic Pulsed | Diagnostic Ultrasound | | | | | |
| Name(s): | Doppler Imaging | Echo Imaging System | Transducer | | | | | |
| | System | | | | | | | |
| Regulation | 21 CFR 892.1550 | 892.1560 | 892.1570 | | | | | |
| Number: | | | | | | | | |
| Product Code: | IYN | IYO | ITX | | | | | |
| Classification | Radiology | | | | | | | |
| Panel: | | | | | | | | |
| Predicate Devices: | ZONARE's ZS3 Ultra | asound System | K120703 | | | | | |
| | ZONARE's ZS3 & z. | one.proUltrasound System | K141641 | | | | | |

Device Description

The ZS3 and z.one_{pro} Ultrasound Systems (hereafter referred to as "ZS3 Ultrasound Platform" or "ZS3" for simplicity) are full-featured, general purpose, software controlled, diagnostic ultrasound systems used to acquire and display high-resolution, real-time ultrasound data through multiple imaging modes. The platform utilizes ZONARE's patented zone technology which allows the system to collect more data at one time, thereby optimizing image quality.

The exam dependent default settings for the ZS3 allows the user to have minimum adjustment for imaging the patient, while the in depth soft-menu control enables the advanced user to set the system

based on image appearance preference. The architecture of the ZS3 Ultrasound Platform supports system integration to a variety of upgradable options and features. Up to three ZONARE transducers can be connected to the multi-transducer port permitting easy transducer transition. The ZS3 Ultrasound Platform can be operated on either battery or AC power.

Intended Use

The device is intended for use by a qualified physician for ultrasound evaluation of Ophthalmic; Fetal/obstetric, gynecological; Abdominal (renal, GYN/Pelvic; Intra-operative (abdominal, thoracic, and vascular), Intra-operative neurological; Pediatric: small organ (thyroid, breast, testes, etc), Adult & Neonatal Cephalic; Trans-rectal, Trans-vaginal, Trans-cranial, Trans-esophageal (non-cardiac and cardiac); Musculosketal (conventional & superficial); 3D/4D; Cardiac - Adult/ Pediatric/ Fetal; Echo, Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and contrast imaging and Tissue elasticity.

Comparison of ZONARE ZS3 Ultrasound Platform to the Predicate Devices

| Item | ZS3 Ultrasound Platform | ZS3 | ZS3 and z.one pro Ultrasound |
|------------------|--|--------------------------|------------------------------|
| | (ZONARE Medical Systems) | (ZONARE Medical Systems) | Systems |
| 510(k) Number | Current Submission | K120703 | K141641 |
| Intended Use | Diagnostic ultrasound imaging or fluid flow | Same | Same |
| | analysis of the human body. | | |
| Indications for | The z.one $_{pro}$ is intended for use by a qualified | Same | Same |
| Use | physician for ultrasound evaluation of Ophthalmic; | | |
| | Fetal/obstetric, gynecological; Abdominal (renal, | | |
| | GYN/Pelvic; Intra-operative (abdominal, thoracic, | | |
| | and vascular), Intra-operative neurological; | | |
| | Pediatric: small organ (thyroid, breast, testes, etc.), | | |
| | Adult & Neonatal Cephalic; Trans-rectal, Trans- | | |
| | vaginal, Trans-cranial, Trans-esophageal (non- | | |
| | cardiac and cardiac); Musculoskeletal | | |
| | (conventional & superficial); 3D/4D; Cardiac - Adult/ Pediatric/ Fetal; Echo, Intra-Cardiac; Pelvic; | | |
| | Peripheral vascular; harmonic tissue and contrast | | |
| | imaging and Tissue elasticity. | | |
| Design | Diagnostic zone technology ultrasound based | Same | Same |
| Design | platform | Same | Same |
| Safety Standards | IEC 60601-1 | Same | Same |
| Surety Standards | IEC 60601-2-37 | Sume | Sume |
| | IEC 60601-1-2 | | |
| | ISO 10993-1, -5, 10, -12 | | |
| | AIUM, NEMA UD 2, NEMA UD3 | | |
| Patient Contact | Complies with ISO 10993 | Same | Same |
| Materials | • | | |
| Mode of | B-Mode, M-Mode, PWD Mode, CWD, CD Mode, | Same | Same |
| Operations | Elastorgraphy, Contrast Enhanced, 3D/4D, ECG | | |
| | (for cardiac cycle referenced timing only) | | |
| | Combined Modes include B+CD, B+PW, | | |
| | B+CD+PW, B+M, M+CM, B+CD+M+CM, | | |

| Item | ZS3 Ultrasound Platform | ZS3 (ZONARE Medical Systems) | ZS3 and z.one pro Ultrasound Systems |
|---|---|---|---|
| | (ZONARE Medical Systems) | (ZONAKE Wedical Systems) | Systems |
| Measurements | B+Elastorgraphy and + ECG Trace B-Mode (2D): Depth, Distance, Circ/Area/ Volume M-Mode: Depth, Distance, HR PWD (Manual): Velocity, Velocity Pairs, RI, Accl, S/D, A/B, PI, HR/ PWD (AutoTrace: RI, PI, Accl, S/D, HR, AT, TAMX and TAMN | Same | Same |
| Principle of Operation | Applying high voltage burst to the Piezoelectric material in the transducer and detect reflected echo to construct the diagnostic image | Same | Same |
| Acoustic Output | Track 3:MI, TIS, TIC, TIB (TI Range 0-6.0) Derated I_{SPTA} : 720mW/cm ² maximum, Mechanical Index ≤ 1.9 maximum or Derated I_{SPPA} ≤ 190 W/cm ² max Ophthalmic use: TI = Max (TIS_as, TIC) ≤ 1 ; ISPTA.3 ≤ 50 mW/cm ² ; and MI ≤ 0.23 | Same | Same |
| Transducer Types | Linear Array Curved Linear Array Phased Array Trans-esophageal Pencil Probe Intracavitary | Same | Same |
| Transducer Frequency | 1.0 – 20.0 MHz | Same | Same |
| DICOM Compliant | Yes | Same | Same |
| Special Procedures User Interface | Yes | Same | Same |
| Display Monitor/ Monitor Arm | ZS3: Color 19" Liquid Crystal Display (LCD)/ 2 arm articulation plus tilt and swivel z.one pro: Color 17" Liquid Crystal Display (LCD)/ Tilt and swivel | Color 19" Liquid Crystal Display (LCD)/ 2 arm articulation plus tilt and swivel | Same |
| Scanner | Integrated | Same | Same |
| Transducer Port(s) | Multi-Transducer Port (Three) | Same | Same |
| Dimensions/ Weight | Height, max (in operational use) 157.5cm (62in) Height, min (in operational use) 128cm (50.5in) Height min (displayed lower for transport) 104cm (41in) Width: 51cm (21.1in) Depth: 72cm (28.2) Weight: 65.3kg (144lb) | Same | Same |
| Power Requirements | 100-240V options, ~ 50-60Hz, 6A max | Same | same |
| Rechargeable Battery | Yes (up to 3.0 hour operation per charge) | Same | same |
| Wireless Capability | Yes (IEEE 802.11b/g, Wi-Fi compliant) | Same | Same |

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Summary of Non-Clinical Testing Performed:

The ZS3 and z.one_{pro} Ultrasound Systems were tested in accordance with FDA Guidance Document – Manufacturer's Seeking Clearance for Ultrasound Systems and Transducers. The following testing was completed:

| Test | Method | Result |
|-----------------------------|--------------------------------|--------|
| Mechanical Verification | In accordance with device | PASS |
| | performance specifications | |
| Electrical Safety | In accordance with IEC 60601-1 | PASS |
| EMC Testing | In accordance with IEC 60601- | PASS |
| | 1-2 | |
| Thermal and Acoustic Output | In accordance with IEC 60601- | PASS |
| | 2-37 | |
| Biocompatibility | In accordance with ISO 10993 | PASS |
| Cleaning & Disinfection | In accordance with FDA | PASS |
| | Guidance Document | |
| Software Validation & | In accordance with 62304 and | PASS |
| Verification | FDA Guidance Document | |
| | Principles of Software | |
| | Validation | |

NOTE: ZONARE's ZS3 Ultrasound Platform and transducers do not require clinical studies to support the determination of substantial equivalence.

Conclusion

The ZS3 and z.one_{pro} Ultrasound Systems are substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to ZONARE's ZS3 and z.one ultra Ultrasound Systems. There are no new no new issues of safety and/or effectiveness introduced by the modification proposed when used as instructed.